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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/775,262	02/01/2001	James L. McMenimen	P-9153.02	7232

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EXAMINER
JASMIN, LYNDA C

ART UNIT	PAPER NUMBER
3627	

DATE MAILED: 03/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/775,262	MCMENIMEN ET AL.	
	Examiner	Art Unit	
	Lynda C Jasmin	3627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☒ The proposed drawing correction filed on *21 January 2003* is: a)☒ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Amendment received January 21, 2003 has been acknowledged.

Claim Objections

2. Claim 7 is objected to because of the following informalities: at lines 2 and 3, the recitation the term is "when" should be --on--, and the term "the manufacturing process" lacks proper antecedent basis. Appropriate correction is required.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 6 and 7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 and 8 of copending Application No. 09/775,281. Although the conflicting claims are not identical, they are not patentably distinct from each other because having a customized data set downloadable to the web-enabled information network via the programmer or having a wireless communication with the programmer achieved the same end result of being in data communication with manufacturing.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-5, are rejected under 35 U.S.C. 102(e) as being anticipated by Linberg (6,385,593 B1).

Linberg discloses a medical device manufacturing and supply information management system as claimed including a web-enabled information network (62, 254) having data communication with a manufacturing process (col. 14, lines 41-44), a programmer (20, 252), at least one implanted medical device (10) having specific features including customized features having customized data sets deployed from a known source (col. 14, lines 11-20; via specific identifying information). The web-enabled information network is in bi-directional data communications scheme with the programmer (col. 10, lines 42-46) to store and transfer the customized data set and information about the at least one implanted medical device (col. 16, lines 12-15), and the programmer being in data communication with the implanted medical device (col. 13, lines 61-63). Further, the web-enabled information network includes one of a satellite based telecommunications link and a cellular link (col. 10, lines 60-62).

The at least one implanted medical device (12, 14) includes customized data set relating to specific device functions and/or features for example identification number or name of the implanting institution (via 234, 236, 238). The known source includes at least one of a manufacturing center a hospital with data communications with the web-enabled information network (col. 14, lines 41-44; lines 59-65).

As per claim 7, Linberg discloses a method for managing medical device inventory production to coordinate and maintain a just-in-time inventory on a build-to-order/build-to-replenish production scheme (col. 16, lines 65-67), wherein a manufacturing process and sales distribution hubs (owner or manufacturer to generate bill for the implanted medical components and forward the bill to medical facility) are

synchronized to tract the implantation of a customized medical device (col. 16, 43-65). The method further including maintaining an inventory (via controlling inventory) of all medical devices at the hubs and at the manufacturing facility (col. 15, lines 28-30) and downloading a customized data set (via specific identification) for the device in a programmer transferring the customized data set to a manufacturing plant via the Web-enabled information network to start a build-to-order/build-to-replenish operation (col. 16, lines 12-67).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Linberg (6,385,593 B1).

Linberg discloses system synchronous with various phases of product manufacturing for customized devices and to start various consumption hubs including hospitals, sales offices, distributors and sales representatives on a build-to-order basis and a build-to-order production scheme, as claimed having a Web-enabled information network being in data communication with manufacturing (col. 14, lines 41-44), and the various consumption hubs (medical facility); at least one programmer being in a bi-directional data communication scheme with a Web-enabled information network (col. 10, lines 44-46); and at least one device implanted (10) in a patient taken out of one of the consumption hubs (medical facility) and having a customized data set downloadable to the Web-enabled information network via the programmer to thereby route device information to the manufacturing facility, having access to the Web-enabled information network (col. 15 , lines 17-29).

Linberg fails to explicitly disclose the web-enabled information in data communication with shipping/delivery. However, since Linberg discloses that the system generate transmittal order requiring the owner or manufacturer of remote medical component to transmit a replacement to medical facility therefore, a shipping and delivery process as to be in place. Thus, it is well known it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the teaching of Linberg in data communication with the best shipping/delivery

services in other to facilitate fast delivery and immediate replacement of aging implanted components.

Response to Arguments

9. Applicant's arguments with respect to claims 1-7 have been considered but are moot in view of the new ground(s) of rejection.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynda C Jasmin whose telephone number is (703) 305-0465. The examiner can normally be reached on Monday- Friday (8:00-5:30) alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert P Olszewski can be reached on (703) 308-5183. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7687 for regular communications and (703) 305-7687 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1113.

Lynda C Jasmin
Examiner
Art Unit 3627

lj
March 26, 2003